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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Erich Wanker et al.
Serial No.: 09/463,874
Confirmation No.: 6909
Filed: July 31, 2000
For: NOVEL COMPOSITION AND METHOD FOR THE
DETECTION OF DISEASES ASSOCIATED WITH
AMYLOID-LIKE FIBRIL OR PROTEIN AGGREGATE
FORMULATIONS

Examiner: Olga N. Chernyshev
Art Unit: 1649

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 17th day of January, 2006.


Melissa L. Barlow Lyons

MAIL STOP RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

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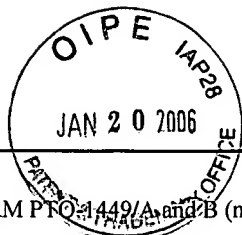
Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

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Docket No.: V0179.70000US00
Date: January 17, 2006
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FORM PTO-1449/A and B (modified PTO/SB/08)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 09/463,874

ATTY. DOCKET NO.: V0179.70000US00

FILING DATE: June 7, 2000

CONFIRMATION NO.: 6909

APPLICANT: Erich Wanker et al.

GROUP ART UNIT: 1649

EXAMINER: Olga N. Chernyshev

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U.S. PATENT DOCUMENTS

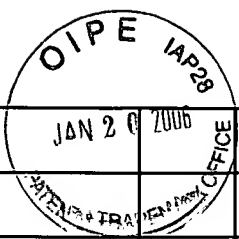
Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

FOREIGN PATENT DOCUMENTS

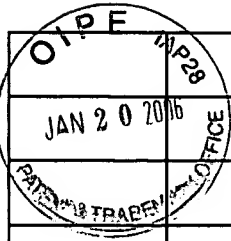
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		Office/ Country	Number	Kind Code			

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		BATES, G.P. et al., Transgenic models of Huntington's disease. Hum Mol Genet. 1997;6(10):1633-7.	
		BECHER, M.W. et al., Intranuclear neuronal inclusions in Huntington's disease and dentatorubral and pallidoluysian atrophy: correlation between the density of inclusions and IT15 CAG triplet repeat length. Neurobiol Dis. 1998 Apr;4(6):387-97.	
		BEYREUTHER, K. et al., Alzheimer's disease. Tangle disentanglement. Nature. 1996 Oct 10;383(6600):476-7.	
		BOOTH, D.R. et al., Instability, unfolding and aggregation of human lysozyme variants underlying amyloid fibrillogenesis. Nature. 1997 Feb 27;385(6619):787-93.	
		BURKE, J.R. et al., Huntingtin and DRPLA proteins selectively interact with the enzyme GAPDH. Nat Med. 1996 Mar;2(3):347-50.	
		CAPUTO, C.B. et al., Amyloid-like properties of a synthetic peptide corresponding to the carboxy terminus of beta-amyloid protein precursor. Arch Biochem Biophys. 1992 Jan;292(1):199-205.	
		CAUGHEY, B. and CHESEBRO, B. Prion protein and the transmissible spongiform encephalopathies. Trends Cell Biol. 1997; 7: 56-62.	
		DE ROOIJ, K.E. et al., Subcellular localization of the Huntington's disease gene product in cell lines by immunofluorescence and biochemical subcellular fractionation. Hum Mol Genet. 1996 Aug;5(8):1093-9.	
		DIFIGLIA, M. et al., Aggregation of huntingtin in neuronal intranuclear inclusions and dystrophic neurites in brain. Science. 1997 Sep 26;277(5334):1990-3.	
		DIFIGLIA, M. et al., Huntingtin is a cytoplasmic protein associated with vesicles in human and rat brain neurons. Neuron. 1995 May;14(5):1075-81.	
		DUYAO, M.P. et al., Inactivation of the mouse Huntington's disease gene homolog Hdh. Science. 1995 Jul 21;269(5222):407-10.	
		GEORGALIS, Y. et al., Huntingtin aggregation monitored by dynamic light scattering. Proc Natl Acad Sci U S A. 1998 May 26;95(11):6118-21.	
		GLENNER, G.G. Amyloid deposits and amyloidosis. The beta-fibrilloses (first of two parts). N Engl J Med. 1980 Jun 5;302(23):1283-92 and 1333-1343.	
		GOLDBERG, Y.P. et al., Cleavage of huntingtin by apopain, a proapoptotic cysteine protease, is modulated by the polyglutamine tract. Nat Genet. 1996 Aug;13(4):442-9.	
		HDCRG. A novel gene containing a trinucleotide repeat that is expanded and unstable on Huntington's disease chromosomes. The Huntington's Disease Collaborative Research Group. Cell. 1993 Mar 26;72(6):971-83.	



	HOLMBERG, M. et al., Spinocerebellar ataxia type 7 (SCA7): a neurodegenerative disorder with neuronal intranuclear inclusions. <i>Hum Mol Genet.</i> 1998 May;7(5):913-8.	
	HOOGEVEEN, A.T. et al., Characterization and localization of the Huntington disease gene product. <i>Hum Mol Genet.</i> 1993 Dec;2(12):2069-73.	
	IGARASHI, S. et al., Suppression of aggregate formation and apoptosis by transglutaminase inhibitors in cells expressing truncated DRPLA protein with an expanded polyglutamine stretch. <i>Nat Genet.</i> 1998 Feb;18(2):111-7.	
	IKEDA, H. et al., Expanded polyglutamine in the Machado-Joseph disease protein induces cell death in vitro and in vivo. <i>Nat Genet.</i> 1996 Jun;13(2):196-202.	
	JARRETT, J.T. and LANSBURY, P.T. Seeding "one-dimensional crystallization" of amyloid: a pathogenic mechanism in Alzheimer's disease and scrapie? <i>Cell.</i> 1993 Jun 18;73(6):1055-8.	
	KALCHMAN, M.A. et al., HIP1, a human homologue of <i>S. cerevisiae</i> Sla2p, interacts with membrane-associated huntingtin in the brain. <i>Nat Genet.</i> 1997 May;16(1):44-53.	
	KALCHMAN, M.A. et al., Huntingtin is ubiquitinated and interacts with a specific ubiquitin-conjugating enzyme. <i>J Biol Chem.</i> 1996 Aug 9;271(32):19385-94.	
	LI, X.-J. et al., A huntingtin-associated protein enriched in brain with implications for pathology. <i>Nature.</i> 1995 Nov 23;378(6555):398-402.	
	LIM, K. et al., Three-dimensional structure of <i>Schistosoma japonicum</i> glutathione S-transferase fused with a six-amino acid conserved neutralizing epitope of gp41 from HIV. <i>Protein Sci.</i> 1994 Dec;3(12):2233-44.	
	MATILLA, A. et al., The cerebellar leucine-rich acidic nuclear protein interacts with ataxin-1. <i>Nature.</i> 1997 Oct 30;389(6654):974-8. Erratum in: <i>Nature</i> 1998 Feb 19;391(6669):818.	
	ONODERA, O. et al., Toxicity of expanded polyglutamine-domain proteins in <i>Escherichia coli</i> . <i>FEBS Lett.</i> 1996 Dec 9;399(1-2):135-9.	
	PAULSON, H.L. et al., Intranuclear inclusions of expanded polyglutamine protein in spinocerebellar ataxia type 3. <i>Neuron.</i> 1997 Aug;19(2):333-44.	
	PERUTZ, M.F. et al., Glutamine repeats as polar zippers: their possible role in inherited neurodegenerative diseases. <i>Proc Natl Acad Sci U S A.</i> 1994 Jun 7;91(12):5355-8.	
	PORTERA-CAILLIAU, C. et al., Evidence for apoptotic cell death in Huntington disease and excitotoxic animal models. <i>J Neurosci.</i> 1995 May;15(5 Pt 2):3775-87.	
	PRUSINER, S.B. et al., Scrapie prions aggregate to form amyloid-like birefringent rods. <i>Cell.</i> 1983 Dec;35(2 Pt 1):349-58.	
	ROIZIN, L. et al., Neuronal nuclear-cytoplasmic changer in Huntington's chorea. <i>J. Neurol. Sci.</i> 1983; 61: 37-47.	
	ROOS, R.A.C. et al., Nuclear membrane indentations in Huntington's chorea. <i>J Neurol Sci.</i> 1983 Sep;61(1):37-47.	
	ROSS, C.A. When more is less: pathogenesis of glutamine repeat neurodegenerative diseases. <i>Neuron.</i> 1995 Sep;15(3):493-6.	
	RUBINSZTEIN, D.C. et al., Phenotypic characterization of individuals with 30-40 CAG repeats in the Huntington disease (HD) gene reveals HD cases with 36 repeats and apparently normal elderly individuals with 36-39 repeats. <i>Am J Hum Genet.</i> 1996 Jul;59(1):16-22.	
	SATHASIVAM, K. et al., Identification of an HD patient with a (CAG)180 repeat expansion and the propagation of highly expanded CAG repeats in lambda phage. <i>Hum Genet.</i> 1997 May;99(5):692-5.	
	SCHATZ, P.J. Use of peptide libraries to map the substrate specificity of a peptide-modifying enzyme: a 13 residue consensus peptide specifies biotinylation in <i>Escherichia coli</i> . <i>Biotechnology (N Y).</i> 1993 Oct;11(10):1138-43.	
	SCHERZINGER, E. et al., Huntingtin-encoded polyglutamine expansions form amyloid-like protein aggregates in vitro and in vivo. <i>Cell.</i> 1997 Aug 8;90(3):549-58.	
	SHARP, A.H. et al., Widespread expression of Huntington's disease gene (IT15) protein product. <i>Neuron.</i> 1995 May;14(5):1065-74.	
	SITTLER, A. et al., Alternative splicing of exon 14 determines nuclear or cytoplasmic localisation of <i>fmr1</i> protein isoforms. <i>Hum Mol Genet.</i> 1996 Jan;5(1):95-102.	
	SITTLER, A. et al., SH3GL3 associates with the Huntingtin exon 1 protein and promotes the formation of polyglu-containing protein aggregates. <i>Mol Cell.</i> 1998 Oct;2(4):427-36.	
	SKINNER, P.J. et al., Ataxin-1 with an expanded glutamine tract alters nuclear matrix-associated structures. <i>Nature.</i> 1997 Oct 30;389(6654):971-4. Erratum in: <i>Nature</i> 1998 Jan 15;391(6664):307.	



SMITH, D.B. et al., Single-step purification of polypeptides expressed in Escherichia coli as fusions with glutathione S-transferase. Gene. 1988 Jul 15;67(1):31-40.	
TELLEZ-NAGEL, I. et al., Studies on brain biopsies of patients with Huntington's chorea. J Neuropathol Exp Neurol. 1974 Apr;33(2):308-32.	
TOWBIN, H. et al., Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: procedure and some applications. Proc Natl Acad Sci U S A. 1979 Sep;76(9):4350-4.	
TROTTIER, Y. et al., Cellular localization of the Huntington's disease protein and discrimination of the normal and mutated form. Nat Genet. 1995 May;10(1):104-10.	
VONSATTEL, J.-P. et al., Neuropathological classification of Huntington's disease. J Neuropathol Exp Neurol. 1985 Nov;44(6):559-77.	
WANKER, E.E. et al., HIP-I: a huntingtin interacting protein isolated by the yeast two-hybrid system. Hum Mol Genet. 1997 Mar;6(3):487-95.	

EXAMINER:	DATE CONSIDERED:
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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